K001693

OCT 2 4 2000

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
2601 Campus Drive
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Common names for the BSM-4100A device include Bedside Monitor, Patient Monitor, Cardiac Monitor and Vital Signs Monitor. The device has been classified as Class III per the Cardiovascular Device Classification Panel under 21 CFR Part 870.1025, "Physiological Patient Monitor with Arrhytmia Detection and Alarms." per MHX and under 21 CFR 870.2340, "ECG Analysis System" per LOS. Functions of the device have also been classified as Class II by Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Classification Panel as follows: under 21 CFR 870.2300, "Cardiac Monitor (including cardiotachometer and rate alarms)" per DRT; under 21 CFR 870.2700, "Oximeter" per DQA; under 21 CFR 870.1130, "Noninvasive Blood Pressure Measurement System" per DXN; under 21 CFR 870.1110 and 21 CFR 870.1100, "Blood Pressure Computer and Alarm" per DSK and DSJ; under 21 CFR 880.2910, "Thermometer, Electronic, Clinical" per FLL; under 21 CFR 868.2375, "Breathing Frequency Monitor" per BZQ; under 21 CFR 868.1720, "Oxygen Gas Analyzer" per CCL; under 21 CFR 868.1400, "Carbon Dioxide Gas Analyzer" per CCK; under 21 CFR 870.2910, "Radio Frequency Physiological Signal Transmitter" per DRG.

The predicate devices are the Nihon Kohden BMS-8800A Life Scope 14 Bedside Monitor per 510(k) #K944422 and K920154, BSM-1101/1102 Life Scope EC Bedside Monitors per 510(k) #K973918, the ECG-9130K Electrocardiograph per 510(k) #K984504, and the Colin Medical Instruments Press-Mate Advantage Bedside Monitor per 510(k) #K973637,

The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2) noninvasive blood pressure (NIBP) invasive blood pressure (IBP), body temperature, Cardiac Output (CO), oxygen concentration (FiO_2), CO_2 and $EtCO_2$, and respiratory rate. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. This device may also be used to condition and transmit physiological signals via radio frequency. This device will be available for use by medical personnel on patient populations within a medical facility.

The device complies with IEC 601-1 subclause 56.3(c) implemented by 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables. To date, no other special controls or performance standards are known or established for this device.

The BSM-4100A device is not sterile.

The device does not directly contact patients. Accessories that contact patients, such as probes and thermistors, are the same accessories as used with other legally marketed products or are comprised of the same component materials as the predicate accessories. Therefore, good laboratory practice studies were not required per 21 CFR part 58.

The BSM-4100A Life Scope P Bedside Monitor was subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of the device. The results confirmed that the device performed within specifications.

Therefore, Nihon Kohden believes that the device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2000

Ms. Bonnie Bishop
Regulatory Affairs Manager
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Re: K001693
Nihon Kohden BSM-4100A Series Life Scope P
Bedside Monitor and accessories
Regulatory Class: III (three)
Product Code: MHX
Dated: September 21, 2000
Received: September 22, 2000

Dear Ms. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K001693

Device Name: BSM-4100A Series Life Scope P Bedside Monitors

Indications for Use:

The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to generate audible and/or visible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2) noninvasive blood pressure (NIBP) invasive blood pressure (IBP), body temperature, Cardiac Output (CO), oxygen concentration (FiO_2), carbon dioxide concentration (CO_2 and $EtCO_2$), and respiratory rate. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. This device may also be used to condition and transmit physiological signals via radio frequency.

The device will be available for use by medical personnel on patients within a medical facility including adults, children and infants.

The ECAPS 12 interpretive ECG program is limited for use with patients age 3 years to adult. The interpretation is intended to provide an assessment of ECG waveform rhythm and morphology to assist the physician in diagnosis and is not intended as the sole basis for diagnosis. All assessments provided by the interpretation program are recommended for review by qualified physicians trained in electrocardiography.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001693